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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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DR. D. GRAESER LTD. 9003 FLORIN WAY UPPER MARLBORO, MD 20772			EXAMINER SMITH, PHILIP ROBERT	
			ART UNIT 3739	PAPER NUMBER
			NOTIFICATION DATE 04/19/2010	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/529,965

Applicant(s)

GAVRIELY, OREN

Examiner

PHILIP R. SMITH

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Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 January 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12, 15 and 18-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12, 15 and 18-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 March 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Paper No(s)/Mail Date _____
- 6) ☐ Other: _____

DETAILED ACTION

Drawings

- [01] The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the microphones, thermal sensors and gas sensors must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.
- [02] Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112, Paragraph One

- [03] The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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- [04] Claim(s) 21 is/are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.
- [05] Claim 21 recites that "the imaging sensor is selected from the group consisting of microphones, thermal sensors and gas sensors." The specification does not disclose an imaging sensor that is selected from such a group.

Claim Rejections - 35 U.S.C. 112, Paragraph Two

- [06] The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
- [07] Claim(s) 21 is/are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
- [08] Claim 21 recites that "the imaging sensor is selected from the group consisting of microphones, thermal sensors and gas sensors." An imaging sensor can not be selected from such a group.

Claim Rejections - 35 USC § 102

- [09] The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
- [10] Claims 12, 15, 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Pirak (5,400,771) for the same reasons set forth in the Office action of 10/21/09. The 'ultrasound embodiment' of Pirak is still anticipatory of claims 12, 15, 18. The 'camera embodiment' of

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Pirak is equally applicable to claims 12, 15, 18, and better suited than the 'ultrasound embodiment' for application to the new claims – 19-22. See below.

- [11] Claims 12, 15, 18, 20, 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Pirak (5,400,771).
- [12] With regard to claim 12: Pirak discloses a method of continuously monitoring changes in indications of vital functions of a patient,
- [12a] employing a tube ("endotracheal tube assembly" 1/65) used to effectively convey fluids into and out of the body of said patient ("connected to a respirator machine" 5/16), wherein said tube is an endotracheal tube,
- [12b] wherein at least one imaging sensor is incorporated in the anterior face of said tube ("video camera 34" 5/9), and wherein said sensor is coupled to a conduit, continuously acquiring signals and transmitting signals via said conduit ("bundle 26" 4/54); said method comprises collecting said signals transmitted via said conduit and interpreting said signals and/or displaying said signals ("connected to a video monitor 36" 4/53);
- [12c] thereby performing said continuous monitoring of changes in indications of vital functions of said patient;
- [12d] wherein said tube is placed within said body of said patient for a substantial period of time, wherein said substantial period of time is a prolonged endotracheal intubation and wherein said continuous monitoring is performed during at least a substantial portion of said period ("during a subsequent surgical operation..." 5/17-19); and

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- [12e] wherein said fluids are selected from the group consisting of: gases and liquids, and conveyed to sustain a vital function of said patient, concomitantly with said monitoring ("respirator" as noted above).
- [13] With regard to claim 15: Pirak discloses that said signals are images ("video monitor" as noted above).
- [14] With regard to claim 18: Pirak discloses endotracheal intubation (as noted above).
- [15] With regard to claim 20: said imaging sensor comprises a camera (as noted above).
- [16] With regard to claim 22: Pirak's discloses continuous monitoring of changes in indications of vital functions of a patient comprising one or more of accumulation of secretions or development of excessive or diminished lung noises, or a combination thereof.
- [16a] Any accumulation of secretions within the field of view of Pirak's camera will inherently be observable if Pirak's device is used precisely as intended. Therefore, the continuous monitoring disclosed by Pirak inherently includes continuous monitoring of accumulation of secretions.
- [16b] Note: Pirak's device continuously compares ("comparator 40... every twenty seconds" 5/20) a live image to a reference image, and sounds an alarm if a significant difference between the two is observed. Pirak explicitly foresees an alert if or when the tube shifts or slips with respect to the patient. However, *any* significant difference between the live image and the reference image, *no matter the cause*, will inevitably trigger the alarm. Moreover, the claims stop short of actually reciting any response to the monitored signals; the claims merely recite "continuous monitoring of changes." Therefore, no "comparator 40" or alarm is necessary to anticipate the claim; the mere presence of a camera in Pirak's tube

anticipates "continuously acquiring signals" and "thereby performing continuous monitoring of changes in indications of vital functions of said patient."

Claim Rejections - 35 USC § 103

- [17] The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
- [18] Claim(s) 19 is/are rejected under 35 U.S.C. 103(a) as being unpatentable over Pirak (5,400,771) in view of Hill (2003/0078476).
- [19] With regard to claim 19: Pirak discloses an imaging sensor ("video camera 34" 5/9), as noted above. Pirak does not disclose that said imaging sensor comprises a CCD or a CMOS chip. It is well known to provide a camera in the form of a CCD or CMOS chip. Hill discloses the following in [0035]:

The light sensor 70 may be either a CCD or a CMOS camera chip. These camera chips consist of light detecting sites or photosites arranged in a grid pattern which record images of the light patterns that shine on their surface. Hence, the resolution of these camera chips is related to the number of pixels in the array as well as the imaging optics of the remainder of the optical system 46. A CMOS camera chip may be preferable to a CCD camera chip since, in general, CMOS camera chips have low power consumption, can provide a direct digital output and are small in size. However, some CMOS camera chips will provide an analog output signal that is encoded in a video format such as PAL, NTSC, S-video, etc. Accordingly, a video capture card must be used with such CMOS camera chips to provide analog to digital conversion. Alternatively, other CMOS camera chips have digital outputs consisting of a 4, 8 or 16 bit data bus.

- [19b] At the time of the invention, it would have been obvious to a person of ordinary skill in the art to provide a CCD or CMOS in the device of Pirak. A skilled artisan

would be motivated to do so because CCDs and CMOS chips have well-known advantages.

Allowable Subject Matter

- [20] Claim(s) 21 is/are would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Response to Arguments

- [21] Applicant's arguments filed 1/21/2010 have been fully considered but they are not persuasive.
- [22] Applicant contends that Pirak teaches "perform[ing] the monitoring only to determine the position of the endotracheal tube within the patient, and not to determine changes in indications of vital functions of the patient." Applicant appears to concede that Pirak teaches monitoring. His purpose is irrelevant since he inevitably achieved every recited step in Applicant's method, which consists of acquiring images and displaying images.
- [23] Applicant further contends that "[a]ny alerts generated **only** relate to the position of the tube itself and not to any of the patient's vital functions" (emphasis added).
- [23a] This is not accurate. Pirak certainly intends that an alert be generated if the position of the tube changes. But *any* significant difference between a live image and a reference image, *no matter the cause*, will register with "comparator 40" and result in an alert. If, for example, an accumulation of secretions appeared within the live image, the difference would register with the comparator, and an alert would inevitably issue, regardless of whether Pirak intended that this be so.

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[23b] Moreover, no alert is necessary to constitute "monitoring" (as noted in [16b]).

Therefore, even if Pirak had designed his device to issue an alert *only* when the tube shifted, the device would still be "monitoring" "vital functions" so long as they manifested themselves visually within the field of view of the "video camera 34." In common usage, the term "monitoring" may imply scrutiny and, if deemed necessary, responsiveness. But implications are not imported into the claim. When the step of "monitoring" is broadly interpreted, it is anticipated by any disclosed means for observation.

Conclusion

[24] **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

[25] A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

[26] Any inquiry concerning this communication or earlier communications from the examiner should be directed to PHILIP R. SMITH whose telephone number is (571)272-6087 and whose email address is philip.smith@uspto.gov. The examiner can normally be reached between 9:00am and 5:00pm.

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- [27] If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272 4764.
- [28] Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Philip R Smith/
Examiner, Art Unit 3739

/Linda C Dvorak/
Supervisory Patent Examiner, Art Unit 3739